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In the

Supreme Court of the United States

J.E.M. AG SUPPLY, INC. (doing business as Farm Advantage, Inc.) FARM ADVANTAGE, INC., LARRY BENZ, MERLE PRUETT (doing business as Siouxland Seeds, Inc.), KEVIN WOLFSWINKEL, TIM KAMSTRA, AND TOM EISCHEN SEED & CHEMICALS,

Petitioners,

v.

PIONEER HI-BRED INTERNATIONAL, INC.,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF RESPONDENT SUPPORTING AFFIRMANCE

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INTEREST OF THE *AMICUS*

The American Intellectual Property Law Association is a national association of more than 12,000 members whose interests lie in patent, copyright, trademark, trade secret and other areas of intellectual property law. The AIPLA's members include attorneys in private practice and attorneys employed by corporations, universities, and government, who represent both owners and users of intellectual property. Unlike many other areas of practice in which separate and distinct plaintiffs' and defendants' bars exist, most, if not all, intellectual property attorneys represent both intellectual property owners and alleged infringers.

The AIPLA has no stake in either of the parties to this litigation or the result of this case, other than its interest in seeking correct and consistent interpretation of the law affecting intellectual property.[1]

[1] Pursuant to Rule 37.3, the parties have consented to the filing of this amicus brief. Their letters of consent have been filed with the Clerk of the Court. None of the parties to this case or their counsel have contributed either substantively or monetarily to the preparation of this brief. Specifically, only the *amicus*, its members and its counsel have made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The general issue of this appeal is whether sexually reproducing plants, more specifically hybrid and inbred corn plants, are excluded from the scope of 35 U.S.C. § 101 and, accordingly, are not permissible subject matter for a utility patent.

As this Court made clear in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("*Chakrabarty*"), and the Federal Circuit reaffirmed in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999), section 101 is compendious and inclusive and admits any subject matter that is produced by man. Section 101 contains no limiting language that would exclude plants from its scope.

Nor can either the Plant Patent Act of 1930 (35 U.S.C. § 161 et seq.) ("PPA") or the Plant Variety Protection Act of 1970 (7 U.S.C. § 2321 et seq.) ("PVPA") reasonably be read as a *post hoc* limiting amendment of section 101. Instead, each was intended to facilitate, not restrict, the availability of protection for plants. Each provided a limited form of protection based on relaxed requirements for disclosure.

The drafters of the PPA and PVPA were motivated by a belief that inventors of plants could not meet the stringent disclosure requirements of a utility patent, or that there was some overriding "product of nature" doctrine that operated to foreclose utility patent protection for any living matter. However, subsequent history and the ongoing development of technology have shown that those rationale no longer apply. Inventors of plants are now able to provide the enabling disclosure and claims required by 35 U.S.C. § 112. *See Pioneer Hi-Bred International, Inc. v. J.E.M. Ag Supply et al.*, 200 F.3d 1374, 1375 (Fed. Cir. 2000) ("*Pioneer*") ("precision of description no longer an insurmountable obstacle"). Authoritative court decisions have explained that inventions made or altered by man are patentable, even if they are living

matter. *See, e.g., Chakrabarty,* and *In re Bergy et al.*, 596 F.2d 952 (CCPA 1979) *aff'd sub. nom., Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (*"Bergy"*) (genetically engineered microorganisms and cultured microorganisms are patentable subject matter).

As a matter of straightforward statutory construction, the PPA and PVPA are inclusive adjuncts to utility patent protection, not exclusive substitutes for it. Even if, by enacting the PPA and PVPA, Congress intended to provide a form of protection for plants that it believed at the time was not provided by section 101, this Court's *Chakrabarty* decision interpreted section 101 more broadly, as encompassing all products of human ingenuity.

Policy considerations lead to the same conclusion. Allowing inventors of plants to obtain a limited period of exclusivity in return for full disclosure is fully consonant with the overriding purpose of the patent laws. The public benefits when plant inventors provide the full disclosure required for a utility patent, in contrast to the limited disclosure provided by plant patents or PVPA certificates. No policy reason justifies discriminating against, and denying utility patent protection to, an inventor who can meet the disclosure requirements of 35 U.S.C. § 112 merely because the invention is embodied in a plant. Rather, in recent years, utility patent protection for plants has assisted progress in many areas of agricultural science.

ARGUMENT

I. Extending the Protection of Utility Patents to Plants Does Not Contradict the PPA or PVPA.

A. The Barriers that Gave Rise to Legislative History Suggesting that the PVPA Was the Sole Route to Protect Sexually Reproducing Plants Had Vanished by the Time of *Hibberd*.

The parties do not dispute that both the PPA and the PVPA were enacted due to the difficulties encountered by plant breeders attempting to meet the written description requirement of 35 U.S.C. § 112(1) and to overcome the doctrine that "products of nature" are not patentable subject matter under 35 U.S.C. § 101. *See Chakrabarty*, 447 U.S. at 311-12, *Imazio Nursery Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1563 (Fed. Cir. 1995), *cert. denied*, 518 U.S. 1018 (1996), *Bergy*, 596 F.2d at 982-84. However, while Petitioner Farm Advantage argues here that the legislative history of these two acts evidences that Congress intended to exclude plants from the ambit of section 101, a better view is that the acts were intended to complement section 101 protection, not to balkanize it by removing subject matter piecemeal from its scope.[2] Today, the scope of subject matter relating to plants that can meet the requirements of section 112 far exceeds single plant varieties, as defined by either the PPA or the PVPA.

In contrast, the protection afforded by plant patents and PVPA certificates extends only to plant "varieties."[3] This

[2] In *Bergy*, the court reasoned that living cells are compositions of matter. *Bergy* 596 F.2d at 985 ("When we examine 'living' cells, it appears that they too are chemical compounds assembled in infinite complexity with an added facility for replication."). It follows, without question, that multicellular organisms, such as plants and animals, fit this definition. Were Farm Advantage to prevail here, plants would not be patentable under section 101, but animals would continue to be patentable. See, for example, Leder et al., U.S. Pat. No. 4,736,866 ("Harvard mouse patent").

[3] In *Imazio Nursery Inc. v. Dania Greenhouses*, 69 F.3d 1560, 1567 (Fed. Cir. 1995), the court quoted the definition of "variety" given in the Plant Variety Protection Act of 1970 (PVPA) at 7 U.S.C. § 2401 (a)(9)(1994):

> The term "variety" means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully

limited protection would not encompass the hybrid corn plants and seed covered by Pioneer's patents.[4] And, while that protection may have met the need to protect new varieties invented or discovered through the 1970s, by the early 1990s agricultural biotechnologists could transform major field crops with genes preselected or mutated to add desired characteristics. After being introduced into a single fertile plant by direct gene transfer or tissue culture techniques, the gene could be tracked by increasingly sophisticated analytical techniques as it was moved throughout the target species by conventional breeding or propagation techniques. Once one plant could be transformed, other plants might theoretically benefit from the new gene. *See, e.g.*, J. D. Watson et al., *Recombinant DNA*, Scientific American Books (2d ed. 1992) at 273-90 and 471-81. The ability of plant scientists to alter and improve plants, therefore, had extended far beyond the creation of new varieties by conventional sexual cross breeding or asexual propagation. The claimed subject matter in question in *Hibberd* was not a "variety" of corn. Rather, some of the claims were directed to all corn, inbred or hybrid, that contained a gene altered so that the seed was high in the amino acid tryptophan. *See Hibberd*, at 227 USPQ at 463, claim 249.

> met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be [propagated] by seed, transplants, plant, tubers, tissue culture plantlets and other matter.

Nurseries sell varieties of vegetables and flowers, such as varieties of tomatoes or tulips, to consumers.

[4] Hybrid corn plants are not "varieties" since they lack the ability to be propagated unchanged. *See* Petitioner's Brief on Pet. for Writ of Cert. at pages 4-5; 7 U.S.C. § 2402.

Also, by 1985, the two factors thought to prevent living organisms from being patentable subject matter, the "product of nature" doctrine and the inability adequately to describe the plant in writing, had vanished in the wake of both judicial decisions and progress in biochemical analysis. In fact, there were no rejections of the claims before the Board in *Hibberd* based on either the product of nature doctrine or the written description requirement of section 112. The claimed genetically engineered corn plants were found to be a type of subject matter that clearly fell within section 101 and that met all the other requirements of patentability. As summarized by the Court of Appeals for the Federal Circuit in its decision in this case:

> Now, however, mankind is learning how to modify plants in ways unknown to nature. In addition, precision of description is no longer an insurmountable obstacle, due to both rules authorizing the deposit of new species in publicly available depositories, and advances in botanical understanding and analysis.

Pioneer, 200 F.3d at 1376.

B. Utility Patents Are Complementary to Plant Patents or PVPA Protection.

Section 101 is not fatally inconsistent with the Plant Patent Act or PVPA according to the applicable legal tests. Specifically, if two statutes "are upon the same subject, the rule is to give effect to both if possible. . . . There must be a positive repugnancy between the provisions of the new law, and those of the old; and even then the old law is repealed by implication only *pro tanto* to the extent of the repugnancy." *United States v. Borden*, 308 U.S. 189 (1939). Contrary to the interpretation urged by Petitioner Farm Advantage, this

Court in *Food and Drug Administration v. Brown & Williamson Tobacco Co.*, 529 U.S. 120 (2000), did not find "repugnancy" between acts of Congress regulating tobacco and the Federal Food, Drug and Cosmetic Act ("FDCA"). Rather, this Court concluded that, facially, the FDCA could not be read logically to encompass the regulation of tobacco. *See* 529 U.S. at 142 ("Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction."). Thus, rather than removing tobacco from the ambit of the FDCA, this Court held that the later passage of acts regulating tobacco simply "ratified . . . the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed." 529 U.S. at 159.

In contrast, the breadth of the language of section 101 was recently reaffirmed by the Federal Circuit in *Pioneer*, 200 F.3d at 1376 ("the policy underlying the patent system fosters its application to all areas of technology-based commerce"). This holding is entirely consistent with *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), in which the Federal Circuit made clear:

> The plain and unambiguous meaning of § 101 is that any invention falling within one of the four stated categories of statutory subject matter may be patented, provided it meets the other requirements for patentability set forth in Title 35, i.e., those found in §§ 102, 103, and 112, ¶ 2.

Therefore, far from being "repugnant" to the purposes of the PPA and PVPA, the issuance of utility patent protection for such potentially important inventions as improved plants should be seen as an appropriate application of the patent statute to encourage further advances in a technology that has already far surpassed the limited boundaries of protection afforded by the PPA and PVPA.

C. The PVPA Is Not "Specific" for Sexually Reproducing Plants.

1. Plants can be propagated both sexually and asexually.

The crux of Petitioner Farm Advantage's argument is that the PVPA is the sole means of protection that Congress intended to provide for sexually reproducing plants. The expansive *Chakrabarty* holding was tempered by the language that utility patent protection would not be available for "organisms produced by genetic engineering" if Congress passed a statute specific to this particular type of invention. *See* 447 U.S. at 318. Even extrapolating this holding from microorganisms to sexually reproducing plants, however, the PVPA act lacks the specificity alleged by Farm Advantage.

While a plant variety capable of sexual reproduction is protectable by PVPA certificate, it is also protectable by a plant patent, so long as the plant variety can also be asexually reproduced. These two modes of propagation were never exclusive; one was simply faster or more convenient for the plant breeder for a given species.[5]

If Farm Advantage chooses to argue that the PVPA was intended to be the exclusive means of protection for plants that are *solely* capable of sexual reproduction, the Court is reminded that many species of plant, including corn, are now capable of being cloned – i.e., reproduced asexually from tissue cultures such as those claimed by Hibberd et al. As noted by the PTO Examiner in *Hibberd*, the claimed tissue cultures of corn were "asexually propagating material."

[5] For example, while apple trees are often propagated asexually by grafting or by cuttings, they can be grown from seed as well. *See, e.g.*, Luby et al., U.S. Plant Pat. No. 7,197 (apple tree variety produced by sexual cross, then asexually reproduced). Turfgrass is propagated by seed, but is also propagatable asexually. *See, e.g.*, Kaerwer, U.S. Plant Pat. No. 4,465 (bluegrass plant asexually or vegetatively propagated).

Hibberd, 227 USPQ at 447. The PVPA explicitly recognizes this dichotomy by prohibiting infringing acts "even in instances in which the variety is multiplied other than sexually. . . ." 7 U.S.C. § 2541. Thus, whether or not it was ever intended by Congress, the exclusivity of subject matter for the PVPA does not in fact exist.

To hold that the PVPA is the only protection available for sexually reproduced plants would also contradict the holding in *Chakrabarty* repudiating the position that "unanticipated inventions are without protection [in patent law]." 447 U.S. at 317. As discussed above, plant patents and PVPA certificates provide protection only for the discoverer or inventor of a new plant "variety," whereas agricultural biotechnology has provided methods to transform entire species, families and even genera of plants. The ability of the patent system effectively to encompass and serve cutting-edge plant science and biotechnology should not be destroyed.

II. The Useful Art of Agriculture Has Been Advanced by the Availability of Multiple Modes of Protection.

A. Utility Patents for Plants Provide a Greater Benefit to the Public than Plant Patents or PVPA.

To support its argument that there are "irreconcilable conflicts [between 35 U.S.C. and] the more specific PVP act," Petitioner Farm Advantage extensively has presented some of the many differences between the scope of protection of PVPA certificates and utility patents for plants.[6] However, the manifest differences between the terms of the two acts also include the fact that the public receives much more from the disclosure of a utility patent on a plant than it does from a PVPA certificate. Therefore, the "conflicts" are actually an

[6] *See, e.g.*, Brief for Petitioners at pages 22-24.

expression of the balance between the inventor's right to exclude and the public's right to full possession of the invention.

Even if the subject matter that is dedicated to the public upon expiration is facially identical (e.g., a plant variety), the amount of technical information that can be employed by the public upon expiration of a utility patent is much greater than upon expiration of a PVPA certificate. This is because a utility patent specification must fully enable the practice of the invention by the interested worker, and must contain an adequate written description of the invention. *See* 35 U.S.C. § 112, first para. "Enablement concerns teaching one of ordinary skill in the art how to practice the invention." *Fiers v. Revel*, 984 F.2d 1165 (Fed. Cir. 1993).

Furthermore, in many cases, patentees will have made a deposit of seeds or other material in an approved public depository, such as the American Type Culture Collection, to meet the enablement or written description requirement. Such deposits become freely available to the public upon issuance of the patent, and a supply must be maintained by the patentee for the effective life of the patent. United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 2404 (7th ed. Jul., 1998).

In contrast to this complete, unrestricted public access to fully enabling information and materials, there is no provision to release seeds deposited with the Department of Agriculture as a prerequisite to obtaining a PVPA certificate, and no requirement that the application for PVPA certificate contain more than a description of the identifying characteristics of the variety for which protection is sought. *See* 7 U.S.C. § 2422.

Furthermore, in the case of some plants engineered to incorporate a foreign gene or overexpress a native gene, in which the sequence of the gene is known or given in the patent specification, the art has advanced sufficiently so that the written description in the specification *alone* will be

sufficient to enable the skilled worker to reproduce the claimed plant, without the need for a deposit. The subject matter of such utility patents is not a variety that is described in general terms, as in a PVPA application, but is a plant or plant part having a discrete trait, such as herbicide resistance, that can be bred into many varietals, and can be described precisely in words. *See, e.g.,* Lundquist et al. (U.S. Pat. No. 5,554,798). While the plant scientist can obtain and experiment with the plant and seed claimed in a utility patent, even before the patent has expired, during the term or following expiration of a PVPA certificate, the interested researcher is left to obtain a sample of the variety as best he or she can. If the variety has been commercially exploited by the breeder holding the PVPA certificate for a limited part of its term and the stock is then destroyed, it may be very difficult to obtain the variety. *See, e.g., Pioneer Hi-Bred International v. Holden Foundation Seeds Inc.*, 35 F.3d 1226, 1230 (8th Cir. 1994) (Holden "discarded" inbred line). The loss of major benefits to the public that attend the utility patent system in the area of plant science fully justifies maintaining both forms of protection for sexually reproducing plants.

B. The Availability of Utility Patents Has Encouraged Development and Protection of New Plants.

Despite the potential for broad protection of genetically engineered or otherwise improved plants by utility patents, the conventional plant breeder who discovers a distinctive new variety under cultivation or develops one by cross-breeding techniques is still free to use the PPA or PVPA to secure protection for the variety – and many have. From 1930 to 1985, only 5,379 plant patents issued, while from 1985-2000, 11,337 issued. From 1971 to 1984, a total of 1297 PVPA certificates were issued, while from 1985 to January 31, 1999, nearly the same length of time, 2760 were

issued. *Progress Report of the Plant Variety Protection Office* (Jan. 31, 1999). Thus, the availability of utility patents for plants has not discouraged the conventional plant breeder from seeking PPA or PVPA protection. Indeed, as noted by Petitioner Farm Advantage, Pioneer sought and obtained protection for its inbred plants under both the PVPA and by utility patents.[7]

The issuance of the *Hibberd* patent facilitated an explosion of the filing and issuance of utility patents on all aspects of plant science. There are over 1500 pending plant utility applications. *See* PTO Technology Center 1600 and 2900, Biotechnology, Organic Chemistry and Designs, Vital Statistics, 00 Vital Stats. Doc. (Oct. 2000). Researchers in agricultural biotechnology developed new methods to introduce preselected genes into plants to improve their nutritional content or to impart pest or herbicide resistance. Some of these methods proved to be generally applicable, and they led to patents that broadly claimed transgenic species ("corn"), families of plants, and even transgenic "plants" *per se*. Some patents contain claims to multiple types.[8]

Thomas Edison's wish that Congress would develop a patent system that would advance the art of agriculture has come true. *See* S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930). Today, utility patents have issued on both field crops, such as corn, soybeans and cotton, and vegetables, such as tomatoes and squash, having properties enhanced by both conventional breeding techniques and by direct gene transfer.

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[7] This does not raise a "double patenting" issue, since PVPA certificates are not patents. *See* Solicitor General's Amicus Brief on Petition for Writ of Cert. at 19.

[8] *See, e.g.*, Umbeck, U.S. Pat. No. 5,159,135 (transgenic cotton); Lundquist et al., U.S. Pat. No. 5,508,468 (high amino acid corn); Adams et al., U.S. Pat. No. 5,780,861 (stress resistant monocot); Falco et al., U.S. Pat. No. 5,773,691 (product-by-process claim to high lysine plants and corn).

This patenting activity has not deterred farmers from adopting this new technology. *See Bio Editors' and Reporters' Guide to Biotechnology*, Biotechnology Industry Organization, Pub. (2000-2001 ed.). U.S. farmers plant more than 70% of the biotech crops grown globally. For example, in 2000, about 61% of all cotton and about 54% of all soybeans planted in the U.S. were transgenic. *See* A. M. Thayer, 78 *Chem. Eng. News,* 21 (October 2, 2000). These crops are no longer laboratory curiosities; they are in the field.

CONCLUSION

For the foregoing reasons, the AIPLA urges the Court to affirm the opinion of the Federal Circuit, thereby confirming that sexually reproducing plants are within the scope of 35 U.S.C. § 101. An inclusive and expansive patent system has strongly assisted progress in this area for more than 15 years, and its efficacy should be affirmed by this Court.

Respectfully submitted,

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